## **REMARKS**

# Status of the Claims

Claims 47-56 and 89 are pending. Claims 47-50 have been allowed. Accordingly, claims 51-56 and 89 are at issue.

## Request that the Examiner acknowledge Claim 89

Claim 89 was added in the 22 December 2005 Amendment. The Examiner did not comment on this claim, which recites that the benzethonium salt is benzethonium chloride.

# Rejections Under 35 U.S.C. §112, first paragraph

Claims 51 -56 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner contends that while the specification is enabled for the benzethonium salt in the examples (i.e., benzethonium chloride), it is not enabled for formulations comprising any benzethonium salt.

Applicants previously referred to, *inter alia*, U.S. Patent No. 5,753,600 which states that a broad range of benzalkonium salts (e.g. benzethonium salts) can be used a antibacterial agents:

Examples of antibacterial agents to be used in the present invention are the following compounds (B-1) - (B-7)...

(B-7) benzalkonium salts represented by formula (VIII)

Application No.: 10/087,207 3 Docket No.: 05408/100I295-US2

wherein R<sub>12</sub> represents a hydrocarbon group having 8-24 carbon atoms; and Y represents a halogen atom, amino acid, fatty acid, an anionic residue of phosphate, phosphonate, sulfonate, or sulfate having an alkyl or alkenyl group of branched or straight chain 1-30 carbon atoms, and an anionic oligomer or polymer selected from formalin condensates of sulfonized polycyclic aromatic compounds which may have a three or more polymerized styrene sulfonic acid as an essential constituent or a hydrocarbon group as a substituent.

(col. 3, lines 61-62 and col. 5, lines 45-61). In response thereto, the Examiner states:

Examiner still questions other anionic forms of benzethonium salts such as the amino acid and fatty acid benzethonium salts.

#### The Examiner also states:

Applicant provides no data for the various benzalkonium salt forms disclosed by the prior art references in [the] instant application. Note the references disclose salts that can be in the amino acid and fatty acid form. These forms raise concerns since amino acid and fatty acids are known to show activity in many applications

The Examiner provides no basis for his "concerns" regarding the purported activity of amino acids and fatty acids and how such activity would require undue experimentation by a skilled artisan. These concerns are not set forth in U.S. Pat. No. 5,753,600. Instead this patent specifically states that amino acid and fatty acid forms of benzethonium can be used as an antibacterial agent.

Application No.: 10/087,207 4 Docket No.: 05408/100I295-US2

The MPEP refers specifically to enablement situations involving working examples and a claimed genus. Section 2164.03 states:

## WORKING EXAMPLES AND A CLAIMED GENUS

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

Applicants respectfully submit that adequate reasons have not been provided. Unsupported allegations that certain salts of benzethonium (amino acid and fatty acid forms) would raise activity "concerns", in the face of disclosures that specifically teaches using these forms as antibacterial agents, does not establish that a person skilled in the art could not use the genus as a whole without undue experimentation. In the absence of such adequate reasons, applicants request that the enablement rejection be withdrawn.

Application No.: 10/087,207

5

Docket No.: 05408/100I295-US2

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: October 6, 2006

Respectfully submitted

Jason C. Chumney

Registration No.: \$4,781

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant